

## CLAIMS

What is claimed is:

1. An anastomosis apparatus comprising:  
5           a tubular member having an end with an edge adapted to form an opening  
          in a vessel wall; and  
          an occlusion member slidably coupled to the tubular member and adapted  
          to substantially occlude said opening in the vessel wall to form an area of  
          hemostasis.  
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2. The anastomosis apparatus of claim 1 wherein the occlusion member is a  
cannula having a cross-section adapted to substantially occlude said opening  
in the vessel wall.
- 15 3. The anastomosis apparatus of claim 1 wherein the occlusion member  
comprises a first and a second generally coaxial cylinders, and a radially  
expandable member attached to a distal end of said first cylinder to  
substantially occlude said opening in the vessel wall, said first cylinder being  
slidably positioned within said second cylinder.  
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4. The anastomosis apparatus of claim 3 wherein the radially expandable  
member comprises a plurality of bristles extending from said distal end of said  
first cylinder, said bristles having memory shapes that flare outwardly from  
said distal end of said first cylinder.  
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5. The radially expandable member of claim 4 wherein the bristles comprise  
nickel-titanium alloy.

6. The radially expandable member of claim 4 wherein the lengths of the bristles are less than 20 mm.
- 5 7. The radially expandable member of claim 4 wherein the first cylinder is hollow and the bristles are glued, attached, or otherwise fixed to an inside wall of the first cylinder.
- 10 8. The radially expandable member of claim 4 wherein the bristles are restrained by a ring attached to said distal end of the first cylinder.
9. The occlusion member of claim 4 wherein the first cylinder has an outer diameter of less than 8 mm.
- 15 10. The occlusion member of claim 4 wherein the first cylinder comprises polymeric material and/or stainless steel or other metallic material.
11. The occlusion member of claim 4 wherein the second cylinder has an outer diameter of less than 15 mm.
- 20 12. The occlusion member of claim 4 wherein the second cylinder comprises polymeric material and/or stainless steel, or other metallic material.
- 25 13. The anastomosis apparatus of claim 3 wherein the radially expandable member comprises a radially expandable membrane.

14. The radially expandable member of claim 13 further comprising a plurality of fasteners removably attached to the membrane, said fasteners being adapted to attach a graft to the vessel wall.
- 5 15. The radially expandable member of claim 14 wherein the fasteners are removably attached to the membrane by glue.
16. The radially expandable member of claim 14 wherein the fasteners are mechanically removably attached to the membrane.
- 10 17. The radially expandable member of claim 13 wherein the membrane comprises materials selected from the group consisting of: polyethylene terephthalate, polyethylene and polyurethane.
- 15 18. The radially expandable member of claim 13 further comprising a generally cylindrical sheath located coaxially outside the membrane, said sheath being radially expandable with the membrane.
- 20 19. The radially expandable member of claim 18 wherein the sheath comprises nickel-titanium alloy.
20. The radially expandable member of claim 18 wherein the sheath comprises polymeric materials.
- 25 21. The radially expandable member of claim 18 wherein the sheath has a wall thickness of less than about .5 mm.

22. The radially expandable member of claim 18 wherein the sheath overlaps itself in a roll-up fashion.
- 5 23. The anastomosis apparatus of claim 3 wherein the radially expandable member comprises a plurality of expansion members attached to said distal end of said first cylinder, said expansion members supporting a membrane therebetween and being foldable from an expanded position to a collapsed position.
- 10 24. The radially expandable member of claim 23 wherein the expansion members form a substantially convex surface in said expanded position.
- 15 25. The radially expandable member of claim 23 wherein the membrane is dimensioned to block the flow of blood through the opening in the vessel wall.
26. The radially expandable member of claim 23 wherein the expansion members comprise superelastic or shape memory materials.
- 20 27. The radially expandable member of claim 23 wherein the membrane comprises a medically compatible polymer.
- 25 28. The anastomosis apparatus of claim 3 wherein the radially expandable member comprises a membrane attached to said distal end of said first cylinder, said membrane being radially expandable from a collapsed position to an expanded position.

29. The radially expandable member of claim 30 wherein the membrane forms a substantially convex surface in said expanded position.

5 30. The radially expandable member of claim 30 wherein the membrane is dimensioned to block the flow of blood through the opening in the vessel wall.

10 31. The radially expandable member of claim 30 wherein the membrane comprises materials selected from the group consisting of: polyethylene terephthalate, polyethylene and polyurethane.

15 32. The anastomosis apparatus of claim 1, further comprising an adapter coaxially mounted to said tubular member and adapted to pass said occlusion member therethrough.

33. The anastomosis apparatus of claim 32, said adapter further comprising wells adapted to hold needles in a predetermined orientation.

20 34. The anastomosis apparatus of claim 32, further comprising needles mounted in wells in said adapter, said wells holding said needles in an orientation adapted to pierce a vessel wall from the inside out.

25 35. The anastomosis apparatus of claim 34, further comprising fasteners connected with said needles, respectively, said fasteners being adapted to fix a graft to a vessel.

36. The anastomosis apparatus of claim 35, each of said fasteners comprising a clip movable between an open and a closed configuration and having a memory biased to said closed configuration, said clip having a first portion including a first end portion and a second portion including a second end portion; a first mechanical restraint coupled to said first portion of said clip and adapted to bias said first portion toward said open configuration; and a second mechanical restraint coupled to said second portion of said clip and adapted to bias said second portion toward said open configuration.

37. The anastomosis apparatus of claim 36, each of said fasteners further comprising a first release mechanism releasably fixed to said first end portion and adapted to release the bias of said first mechanical restraint against said first portion upon release from said first end portion.

38. The anastomosis apparatus of claim 37, each of said fasteners further comprising a flexible member interconnecting one of said needles with said first release mechanism.

39. The anastomosis apparatus of claim 37, each of said fasteners further comprising a second release mechanism releasably fixed to said second end portion and adapted to release the bias of said second mechanical restraint against said second portion upon release from said second end portion.

40. The anastomosis apparatus of claim 39, each of said fasteners further comprising a second needle releasably fixed to said second release mechanism.

41. The anastomosis apparatus of claim 40, each of said fasteners further comprising a second flexible member interconnecting said second needle with said second release mechanism.

5 42. An anastomosis system comprising:  
a tubular member having an end with an edge adapted to form an opening in a vessel wall; and  
an occlusion member slidably coupled to the tubular member and adapted to substantially occlude said opening in the vessel wall to form an area of  
10 hemostasis.

43. The anastomosis system of claim 42 further comprising an anchor member adapted to hold said vessel wall in place while the tubular member is forming said opening in said vessel wall, said anchor member being slidably coupled  
15 to the tubular member.

44. The anastomosis system of claim 43 wherein the anchor member comprises a shaft and a piercing member extending from a distal end of said shaft, said  
20 piercing member being adapted to pierce the vessel wall.

45. The anchor member of claim 44 wherein said shaft comprises a flexible polymeric material.

25 46. The anchor member of claim 44 wherein the shaft has a diameter of less than 3 mm.

47. The anchor member of claim 44 wherein the piercing member has a tapered end.

5 48. The anchor member of claim 44 wherein the piercing member has a pointed end.

49. The anastomosis system of claim 43 further comprising a generally circular centering disk slidably movable along the piercing member.

10 50. The anastomosis system of claim 49 wherein the centering disk is made from a medically acceptable polymer.

51. The anastomosis system of claim 49 wherein said centering disk comprises ABS or polyurethane.

15 52. The anastomosis system of claim 49 wherein the centering disk comprises one or more spikes extending from a surface of the centering disk proximal of the vessel wall.

20 53. The centering disk of claim 52 wherein said one or more spikes comprise Nitinol.

54. The centering disk of claim 52 wherein said one or more spikes have lengths of less than about 5 mm.

25 55. A cannula comprising a body member forming a lumen and a piercing member extending from said body member, said piercing member having a



generally cylindrical edge adapted to cut tissue and said piercing member forming a cavity adapted to receive the tissue.

56. The cannula of claim 55 wherein said cylindrical edge is pointed.

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57. The cannula of claim 55 further including a rod extending through said lumen, said rod having a pointed member extending therefrom.

58. The cannula of claim 57 wherein said pointed member includes a portion adjacent to said cylindrical edge, said pointed head portion having diameter greater than the inner diameter of said cylindrical edge.

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59. A trocar comprising a body having a proximal portion, a distal portion, and a passageway extending between said proximal and distal portions, said passageway changing in dimension along a longitudinal portion thereof.

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60. The trocar of claim 59 further including a seal disposed within said passageway.

61. A surgical fastener cartridge comprising: a first tubular member; a second tubular member slidably coupled to said first tubular member; and at least one surgical fastener having one end engaging said first tubular member and a second end engaging said second tubular member.

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62. The cartridge of claim 61 wherein said surgical fastener has first and second shapes and said tubular member bias said fastener to said second shape.

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63. The cartridge of claim 62 including a rod disposed in said second cylindrical member and urging said second end of said fastener against said second tubular members.

5 64. A method for performing an anastomosis while maintaining blood flow within a vessel comprising:  
positioning a cannula so that it extends through a vessel wall;  
attaching a graft to the vessel wall adjacent to said cannula while said cannula  
extends through said vessel wall; and  
10 removing the cannula.

65. The method of claim 64 wherein the cannula is positioned in the vessel wall from the interior of the vessel.

15 66. A method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel comprising:  
forming an opening in the blood vessel;  
inserting an occluding member into the opening cut into the vessel,  
thereby occluding the opening; and  
20 anastomosing a graft to the vessel at the opening.

67. The method of claim 66, wherein said forming an opening comprises:  
piercing the vessel wall with an anchor member; and  
cutting the opening in the vessel wall around the anchor member with a  
25 cutting tool.

68. The method of claim 67, further comprising removing a tissue plug produced by said cutting, prior to said inserting an occluding member.

5 69. The method of claim 67, wherein said inserting comprises inserting the occluding member into the opening cut into the vessel while the cutting tool is still in the opening.

10 70. The method of claim 69, further comprising withdrawing the cutting tool to allow the occluding member to expand against the periphery of the opening, thereby occluding it.

15 71. The method of claim 70, further comprising placing a graft over the occluding member and in alignment with the opening, prior to said anastomosing.

20 72. The method of claim 67, further comprising sliding a generally circular centering disk along the anchor member onto the vessel wall, prior to said cutting, thereby clamping vessel wall tissue between the centering disk and an end portion of the anchoring member.

25 73. The method of claim 72, further comprising removing the tissue plug in a clamped configuration between the centering disk and anchoring member.

74. The method of claim 66, wherein said anastomosing comprises fastening walls of the graft and vessel together using fasteners.

75. The method of claim 74, wherein said fastening is performed with self closing fasteners.

5 76. The method of claim 66, wherein the occluding member includes fasteners attached thereto, said method further comprising pulling back said occluding member slightly, after expanding to occlude, thereby piercing the vessel wall with needles attached to said fasteners.

10 77. The method of claim 76, further comprising grasping the needles and pulling them entirely through the vessel wall, thereby positioning the fasteners for performing the anastomosis and separating them from the occluding member.

15 78. The method of claim 77, wherein the fasteners each have a second needle at an end opposite the location of the needles used to pierce the vessel wall, said anastomosing further comprising piercing the graft with the second needles and securing the graft and the vessel together by closing the fasteners upon them.

20 79. The method of claim 67, wherein an adapter is mounted on the cutting tool, the adapter retaining a plurality of needles therein which are prepositioned for piercing the vessel from the inside out, said method further comprising inserting the cutting tool and adapter into the vessel, prior to said inserting an occluding member, so as to position the needles against the inner wall of the vessel, and pulling back the adapter and cutting tool slightly to pierce the  
25 vessel wall with the needles; grasping the needles and pulling them all the way through the vessel and thereby also removing them from the adapter.

80. The method of claim 79, wherein the needles are connected to two-stage release fasteners having independently closable first and second portions, the needles being connected by flexible members to respective first portions of the fasteners, said method further comprising removing the needles and flexible members from the fasteners, after insertion of the occluding member, thereby closing the first portions of the fasteners and fixing the fasteners to the wall of the vessel.

81. The method of claim 80, wherein the fasteners each have a second needle connected to an end portion of the second portion thereof by a second flexible member, said anastomosing further comprising piercing the graft with the second needles and securing the graft and the vessel together by removing the second needles and second flexible members from the second portions of the fasteners, thereby closing the second portions of the fasteners on the graft and fixing the walls of the vessel and the graft in approximation.

82. An occlusion device comprising first and a second generally coaxial cylinders, the first cylinder being slidably positioned within the second cylinder and having a plurality of bristles extending from a distal end of said first cylinder, said bristles having memory shapes that flare outwardly from said distal end of the first cylinder.

83. The occlusion device of claim 82, wherein the bristles are made of super-elastic materials comprising nickel-titanium alloy.

84. The occlusion device of claim 82, wherein the lengths of the bristles extending from the distal end of the first cylinder are of less than about 5 mm.

85. The occlusion device of claim 82, wherein the bristles are fixed to the inside wall of the first cylinder.
- 5 86. The occlusion device of claim 82, wherein the bristles are restrained by a ring attached to the distal end of the first cylinder.
87. The occlusion device of claim 82, wherein the first cylinder has an outer diameter of less than about 3 mm.
- 10 88. The occlusion device of claim 82, wherein the first cylinder has a wall thickness of less than about .5 mm.
- 15 89. The occlusion device of claim 82, wherein the first cylinder comprises a medically compatible polymeric material.
90. The occlusion device of claim 82, wherein the second cylinder has a wall thickness of less than about .5 mm.
- 20 91. The occlusion device of claim 82, wherein the second cylinder comprises a medically compatible polymeric material.
- 25 92. An occlusion device comprising a radially expandable membrane and a plurality of fasteners removably attached to the membrane, said fasteners being adapted to attach a graft onto a vessel.

93. The occlusion device of claim 92, wherein the fasteners are attached to the membrane by glue.

5 94. The occlusion device of claim 92, wherein the fasteners are attached to the membrane through a mechanical fitting mechanism.

95. The occlusion device of claim 92, wherein the membrane comprises a medically compatible polymer.

10 96. An occlusion device comprises a radially expandable membrane and a generally cylindrical sheath located coaxially outside the membrane, said sheath being radially expandable with the membrane.

15 97. The occlusion device of claim 96, wherein the sheath comprises nickel-titanium alloy.

98. The occlusion device of claim 96, wherein the sheath comprises at least one polymeric material.

20 99. The occlusion device of claim 96, wherein the sheath has a wall thickness of less than about .5 mm.

25 100. The occlusion device of claim 96, wherein the sheath overlaps itself in a roll-up fashion, the overlap being greater in the unexpanded configuration and lesser in an expanded configuration.

101. An occlusion device comprising first and a second generally coaxial cylinders and a plurality of expansion members attached to a distal end of the first cylinder, said expansion members supporting a membrane therebetween and being foldable from a collapsed position and an expanded position, and said first cylinder being slidably positioned within said second cylinder.

102. The occlusion device of claim 101, wherein the expansion members form a substantially convex surface in said expanded position.

103. The occlusion device of claim 101, wherein the membrane is dimensioned to block the flow of blood through an opening in a vessel wall.

104. The occlusion device of claim 101, wherein the expansion members comprise superelastic material.

105. The radially expandable member of claim 96 wherein the membrane comprises at least one medically compatible polymeric material.

106. An occlusion device comprising first and second generally coaxial cylinders, and a membrane attached to a distal end of said first cylinder, said membrane being radially expandable from a collapsed position to an expanded position.

107. The occlusion device of claim 102, wherein the membrane forms a substantially convex surface in said expanded position.

108. The occlusion device of claim 106, wherein the membrane is dimensioned to block the flow of blood through the opening in the vessel wall.



109. The occlusion device of claim 106, wherein the membrane comprises at least one material selected from the group consisting of polyethylene terephthalate, polyethylene and polyurethane.

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110. An occlusion device comprising a radially expandable member expandable from a relatively compressed smaller external dimension to a radially expanded, relatively larger external dimension, said radially expanded member fixed to an end of an elongated member; and a cylindrical restrictor adapted to pass over said elongated member and said radially expandable member, thereby compressing said radially expandable member so that it assumes said relatively compressed smaller external dimension.

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111. The occlusion device of claim 110, wherein said restrictor is adapted to slide off of said radially expandable member, thereby allowing said radially expandable member to expand.

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112. A dual-stage release fastener comprising:

a clip movable between an open and a closed configuration and having a memory biased to said closed configuration, said clip having a first portion including a first end portion and a second portion including a second end portion;

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a first mechanical restraint coupled to said first portion of said clip and adapted to bias said first portion toward said open configuration; and

a second mechanical restraint coupled to said second portion of said clip and adapted to bias said second portion toward said open configuration.

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113. The fastener of claim 112, wherein said first and second mechanical restraints are independently manipulatable to allow independent closure of said first and second portions of said clip.

5 114. The fastener of claim 112, further comprising an enlarged first end portion on said first portion and an enlarged second end portion on said second portion.

115. The fastener of claim 114, further comprising first and second retainers fixed on said clip and abutting said first and second mechanical restraints  
10 respectively.

116. The fastener of claim 115, further comprising first and second release mechanisms releasably fastened to said first and second enlarged end portions respectively, said release mechanisms being independently operable to close a  
15 respective first or second portion of said clip upon release from a respective first or second enlarged end portion.

117. The fastener of claim 116, further comprising a first needle fixed to said first release mechanism.  
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118. The fastener of claim 117, further comprising a flexible member interconnecting said first needle and said first release mechanism.

119. The fastener of claim 117, further comprising a second needle fixed to said second release mechanism.  
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120. The fastener of claim 119, further comprising a flexible member interconnecting said second needle and said second release mechanism.

121. The fastener of claim 112, wherein said first and second mechanical restraints comprise first and second coils surrounding at least a portion of said first and second portions of said clip, respectively.

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122. The fastener of claim 121, wherein said first and second coils each comprise a memory biased to said closed configuration and a memory shape substantially conforming to a memory shape of said first and second portions of said clip, respectively.

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